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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to “non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin” and “increase in calcium absorption” pursuant to Article 14 of Regulation (EC) No 1924/2006¹

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ABSTRACT

Following an application from Specialised Nutrition Europe (formerly IDACE), submitted for authorisation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to “non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin” and “increase in calcium absorption”. The scope of the application was proposed to fall under a health claim referring to children’s development and health. The food constituents that are proposed by the applicant to be the subject of the health claim are “non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin”. Upon requests by EFSA for clarification on the food constituent, the applicant did not clarify the food constituent that is the subject of the health claim. The Panel considers that the food constituents, “non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin”, which are the subject of the health claim, are not sufficiently characterised. The Panel concludes that a cause and effect relationship cannot be established between the consumption of “non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin” and a beneficial physiological effect.

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KEY WORDS

non-digestible oligosaccharides, non-digestible polysaccharides, galacto-oligosaccharides, oligofructose, polyfructose, inulin, calcium absorption, health claims

¹ On request from the Competent Authority of France following an application by Specialised Nutrition Europe (formerly IDACE), Question No EFSA-Q-2008-140, adopted on 30 October 2014.

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SUMMARY

Following an application from Specialised Nutrition Europe (formerly IDACE), submitted for authorisation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to “non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin” and “increase in calcium absorption”.

The scope of the application was proposed to fall under a health claim referring to children’s development and health.

The food constituents that are proposed by the applicant to be the subject of the health claim are “non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin”.

Upon requests by EFSA for clarification on the food constituent that is the subject of the health claim (e.g. non-digestible carbohydrates, one out of the four non-digestible carbohydrates indicated by the applicant, or a fixed combination of these four non-digestible carbohydrates), the applicant did not clarify the food constituent that is the subject of the health claim.

The Panel notes that the study products used in the human intervention studies, which were provided by the applicant for this health claim, included a variety of non-digestible oligo- and polysaccharides with variable degrees of polymerisation.

The Panel considers that the food constituents “non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin”, which are the subject of the health claim, are not sufficiently characterised.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of “non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin” and a beneficial physiological effect.

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BACKGROUND

Regulation (EC) No 1924/2006⁴ harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Articles 14 to 17 of this Regulation lay down provisions for the authorisation and subsequent inclusion of reduction of disease risk claims and claims referring to children’s development and health in a Community list of permitted claims.

According to Article 15 of this Regulation, an application for authorisation shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

STEPS TAKEN BY EFSA

- The application was received on 14/02/2008.
- The scope of the application was proposed to fall under a health claim referring to children’s development and health.
- On 26/03/2008, during the validation process of the application, EFSA sent a request to the applicant asking it to provide missing information.
- On 05/08/2013, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 10/10/2013.
- On 21/11/2013, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application, and the clock was stopped on 29/11/2013. On 30/01/2014, EFSA received the requested information and the clock was restarted, in compliance with Article 16(1) of Regulation (EC) No 1924/2006.
- On 06/03/2014, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application, and the clock was stopped on 14/03/2014.
- Since no additional information was received by the applicant, on 23/07/2014 the clock was restarted.
- During its meeting on 30/10/2014, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to “non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin” and “increase in calcium absorption”.

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16 of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: “non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin” and “increase in calcium absorption”.

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of “non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin”, a positive assessment of its safety, nor a decision on whether “non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin” is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 17 of Regulation (EC) No 1924/2006.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Specialised Nutrition Europe (formerly IDACE), 9-31 Avenue des Nerviens, 1040 Brussels, Belgium.

Food/constituent as stated by the applicant

According to the applicant, the food constituents for which the claim is made are non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin.

Health relationship as claimed by the applicant

According to the applicant, as non-digestible oligo- and polysaccharides cannot be digested by human digestive enzymes in the gastrointestinal tract, they arrive in the colon intact. In the colon, they serve as substrates for the intestinal microbiota, favouring the growth of beneficial bacteria. In addition to the beneficial effects on colonic health, non-digestible oligo- and polysaccharides have been shown to increase calcium absorption and bone mineral density in adolescents.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: “With non-digestible oligo- and/or polysaccharides to stimulate calcium absorption”.

As equivalent alternative wordings, the applicant has also proposed: “Non-digestible oligo- or polysaccharides: inulin, galacto-oligosaccharides, fructo-oligosaccharides, oligofructose, polyfructose/soluble dietary fibre/are soluble dietary fibres that/are prebiotic dietary fibres that/stimulate /support/promote/enhance/increase/improve/accelerate/help/calcium absorption/calcium uptake/calcium transfer into the blood”.

Specific conditions of use as proposed by the applicant

The target population proposed by the applicant is infants (from birth onwards) and young children (up to three years of age) as defined in Directive 89/398/EEC on foodstuffs intended for particular nutritional uses.

The applicant has proposed that, to be able to make the claim, the content of non-digestible oligosaccharides should be within the range set in Directive 2006/141/EC on follow-on formulae and Directive 2006/125/EC on processed cereal-based foods.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituents that are proposed by the applicant to be the subject of the health claim are “non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin”.

The Panel noted that non-digestible oligo- and polysaccharides also include non-digestible carbohydrates other than those that were indicated by the applicant to be the subject of the health claim (EFSA NDA Panel, 2010).

Thus, the applicant was requested by EFSA to clarify the food constituent (e.g. non-digestible carbohydrates, one out of the four non-digestible carbohydrates (i.e. “galacto-oligosaccharides, oligofructose, polyfructose and inulin”), indicated by the applicant, or a fixed combination of these four non-digestible carbohydrates) that is the subject of the health claim. The applicant did not clarify the food constituent that is the subject of the health claim.

For the scientific substantiation of an effect of “non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin” on “increase in calcium absorption”, the applicant provided human intervention studies which were carried out with several non-digestible oligo- and polysaccharides (e.g. transgalacto-oligosaccharides, oligofructose, chicory oligofructose, mixture of oligofructose and long-chain inulin or inulin) (Van den Heuvel et al., 1999, 2000; Griffin et al., 2002; Abrams et al., 2005). The Panel notes that the study products used in these human intervention studies included a variety of non-digestible oligo- and polysaccharides with variable degrees of polymerisation.

The Panel considers that the food constituents “non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin”, which are the subject of the health claim, are not sufficiently characterised.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of “non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin” and a beneficial physiological effect.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituents, “non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin”, which are the subject of the health claim, are not sufficiently characterised.
- A cause and effect relationship cannot be established between the consumption of “non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin” and a beneficial physiological effect.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on “non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin” and “increase in calcium absorption” pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0060_FR). February 2008. Submitted by Specialised Nutrition Europe (formerly IDACE).

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